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purpose of optimization of the amounts required for the method of treatment as instantly claimed." Office Action, page 4. However, this alleged "motivation" (the desire to optimize the amounts of the components) presupposes the combination itself, which is central to the present invention. For the reasons described in more detail below, Applicant submits that there is no cognizable motivation to combine the cited references, and that even if such motivation did exist, it would not lead one skilled in the art to the present invention.

Determining obviousness requires an analysis of the invention *as a whole*. *Gillette Co. v. S.C. Johnson & Son, Inc.*, 919 F.2d 720, 724 (Fed. Cir. 1990). Significantly, *Gillette* emphasizes that whether all of the elements of the claimed invention were old in other contexts is immaterial to the issue of obviousness. Rather, "*what must be found obvious to defeat the patent is the claimed combination.*" *Id.* (quoting *Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1448, 223 U.S.P.Q. 603, 609-10 (Fed. Cir. 1984)) (emphasis in original).

It is well settled patent law that "obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art." *See In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 U.S.P.Q.2d 1941 (Fed. Cir. 1992); MPEP § 2143.01.

Furthermore, the fact that a reference or references can be combined or modified is not sufficient to establish obviousness. For example, the Federal Circuit held in *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990), that the mere fact that combination or modification of a reference or references is possible does not establish obviousness of the resultant combination unless the prior art also suggests the desirability of the combination, i.e., unless the prior art provides motivation to produce the resultant combination. *Mills*, 16 U.S.P.Q.2d at 1432; *see also* MPEP § 2143.01, page 2100-91.

Moreover, the Board of Patent Appeals and Interferences has held that the fact that the claimed invention is within the capabilities of one of ordinary skill in the art is not sufficient by itself to establish obviousness. *Ex parte Levengood*, 28 U.S.P.Q.2d 1300 (BPAI 1993). Section 2143.01 of the MPEP explains the *Levengood* holding as follows:

A statement that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill of the art at the time the claimed invention was made" because the references relied upon teach that all aspects of the claimed invention were

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individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references.

MPEP § 2143.01, page 2100-91 (emphasis in original).

The present invention provides methods for treating osteoarthritic mammalian joints by the intraarticular administration of a viscoelastic solution comprising a particular ratio of sodium hyaluronate and chondroitin sulfate. The Examiner correctly notes that Lindblad teaches the use of hyaluronic acid to treat cartilage degeneration. The compositions of Lindblad, however, require high molecular weight hyaluronic acid (molecular weight in excess of 3 million Daltons). Those skilled in the art will appreciate that these high molecular weight hyaluronic acid solutions will be extremely viscous. Lindblad teaches using a concentration of "<2% w/w" for convenient administration. Col. 3, lines 44-45. The compositions of the present claims require 3% sodium hyaluronate combined with 4% chondroitin sulfate. Nothing in the Lindblad reference suggests using a 3% sodium hyaluronate solution, much less such a solution in combination with 4% chondroitin sulfate. Indeed, Lindblad does not suggest any means of improving the straight hyaluronate acid solution described therein. The deficiencies of such a straight hyaluronic acid solution are described by the applicant at page 4 of the present specification.<sup>1</sup> In view of Lindblad's failure to recognize these deficiencies, there is no motivation to modify the formulation described in Lindblad in any manner, much less to make the specific changes required to achieve the presently claimed invention.

The Nocelli reference cited by the Examiner discloses chondroitin sulfate for the treatment of arthrosis. However, the disclosure is limited to oral formulations that would in no way be suitable for intraarticular administration as contemplated by the present invention. There is no reason to believe that the nutritional supplements described in Nocelli would have suitable stability, viscosity, or sterility for intraarticular use. The administration described in Nocelli is "once or twice a day," whereas intraarticular injections such as those contemplated by the present claims are typically separated by weeks or months. There is nothing whatsoever in Nocelli that would motivate one skilled in the art to administer the compositions described therein intraarticularly, or to combine the teachings thereof with the teachings of Lindblad. The Examiner concludes that the idea of combining the two references "flows logically from their having been individually taught in the prior art for the treatment of

<sup>1</sup> The Applicant has found that while the intraarticular application of sodium hyaluronate may relieve inflammation-related symptoms (as disclosed in Lindblad), the effect of conventional hyaluronate is temporary because the highly viscous material remains within the articular chamber for only about 72 hours before it is absorbed and/or metabolized. The residual effects of this substance act on the synovial receptors causing a pain reduction that lasts several weeks and even months. However, this perceived benefit may actually be detrimental because, with symptoms masked, the joint is used with more intensity and degeneration of the cartilage is accelerated.

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mammalian joint exhibiting articular cartilage degeneration." Applicant respectfully submits, however, that such is not the appropriate standard for determining motivation to combine. It is well established that for references to be properly combined in a § 103 rejection, they must suggest to one skilled in the art doing what the applicant has done. In this instance, there is simply no such suggestion.

It is not enough that both references are related to the treatment of joints.

When the references are in the same field as that of the applicant's invention, knowledge thereof is presumed. However, the test of whether it would have been obvious to select specific teachings and combine them has did the applicant must still be met by identification of such suggestion, teaching, or motivation in the prior art, arising from what the prior art would have taught a person of ordinary skill in the field of the invention.

*In re Dance*, 48 U.S.P.Q.2d 1635, 1637 (Fed. Cir. 1998). See also, *Sunrise Medical HHG, Inc. v. AirSep Corp.*, 95 F.Supp. 2d 348, 452 (W.D. PA 2000) ("the mere fact that all of the prior art is within the same field does not, without more, supply a teaching or motivation to combine.") Rather, the cited references must contain "some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant" *In re Kotzab*, 54 U.S.P.Q.2d 1308, 1316 (Fed. Cir. 2000). In this case, neither of the cited references provides any motivation for combination of those references. One reference relates to intraarticular administration while the other relates to an oral nutritional supplement. Neither reference suggests to those skilled in the art that the compositions described therein are in some way deficient for their intended purposes, nor do they suggest to one skilled in the art that they could be improved in any manner. However, even assuming, for the sake of argument, that some general motivation to combine did exist, there is clearly nothing in these two references that would motivate one skilled in the art to arrive at the "specific combination" of components described in the present claims. To the contrary, combining the teachings of Lindblad and Nocelli would yield a therapy comprising the intraarticular administration of a high molecular weight sodium hyaluronate solution in conjunction with daily oral administrations of chondroitin sulfate – not the methods of the present claims.

Applicant respectfully submits that the only way to reach a conclusion of obviousness in view of the cited art is to view that cited art in light of the teachings of the present application. This amounts to an improper "hindsight reconstruction" of the invention based upon the teaching in the present application. See, *In re Fine*, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). In *Fine*, the court explained that

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[t]o imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.

*Fine*, 5 U.S.P.Q.2d at 1600 (quoting *W.L. Gore & Assoc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 U.S.P.Q. 303, 312-13 (Fed. Cir. 1983)).

The rejection under § 103 based on the combination of Lindblad and Nocelli amounts to a "picking and choosing" of certain parts of the references while ignoring other aspects of them. The Federal Circuit has held that "it is impermissible within the framework of 35 U.S.C. § 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference *fairly suggests* to one skilled in the art." *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 230 U.S.P.Q. 416, 419 (Fed. Cir. 1986) (quoting *In re Wesslau*, 353 F.2d 238, 241, 147 U.S.P.Q. 391, 393 (CCPA 1965)). Nothing in Nocelli fairly suggests any intraarticular utility. Consequently the proposed combination of references is improper on its face.

For all the foregoing reasons, applicant respectfully submits that the Examiner's basis for rejection is not well founded, and therefore requests favorable reconsideration of the claims.

Respectfully submitted,



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